REMARKS/ARGUMENTS

The Pending Claims

Claims 1-8, 16, 17, and 19-23 currently are pending. The claims are directed to a nutrition trace element composition comprising selenium and zinc, and a method of using the composition.

The Amendments to the Claims

Claim 1 has been amended to recite that the daily dose of the composition contains 0.5 mg-2 mg of selenium and 10 mg-100 mg of zinc. This amendment is supported by the specification at, e.g., page 12, lines 27-29. Claim 4 has been amended to clarify that the composition exists as a concentrate with 0.05 mg-0.2 mg/ml of selenium and 1 mg-10 mg/ml of zinc. Claim 16 has been amended to comport with the language of claim 1. Claim 23 is new and is supported by the specification at, e.g., page 1, lines 8-9. The claims also have been amended to correct misnumbering and to place the claims in a form more consistent with U.S. law. No new matter has been added by way of these amendments.

The Office Action

The Office Action objects to claim 18 under 37 C.F.R. § 1.75(c) as allegedly being an improper dependent claim. Claims 19 and 21 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Claims 1-6, 16, and 18-22 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Frankel, *Nutrition Research, 13*: 583-596 (1993) ("the Frankel reference"). Claims 1, 4, 6, 16, 17, and 20 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent Application Publication No. 2003/0161863 A1 ("the '863 publication"). Claims 7 and 8 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Frankel reference, while claim 17 is rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Frankel reference in view of the '863 publication. Reconsideration of these rejections is respectfully requested.

Discussion of Claim Objection

Claim 18 is objected to under 37 C.F.R. § 1.75(c) as allegedly being an improper dependent claim. Claim 18 has been cancelled, thereby rendering this objection moot.

Discussion of Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 19 and 21 have been rejected under Section 112, second paragraph, as allegedly being indefinite. Specifically, the Office Action alleges that the phrase "the trace elements" lacks antecedent basis. Claim 16, from which claims 19 and 21 depend, has been amended to recite administration of a nutrition trace element *composition*. Claims 19 and 21 have been amended to refer to the composition rather than "the trace elements." Accordingly, the rejection of claims 19 and 21 under Section 112, second paragraph, should be withdrawn.

Discussion of Rejections Under 35 U.S.C. § 102(b)

Claims 1-6, 16, and 18-22 have been rejected under Section 102(b) as allegedly anticipated by the Frankel reference. Claims 1, 4, 6, 16, 17, and 20 have been rejected under Section 102(b) as allegedly anticipated by the '863 reference. These rejections are traversed for the reasons set forth below.

Claims 1 and 16 have been amended to recite a nutrition trace element composition which contains 0.5 mg-2 mg of selenium and 10 mg-100 mg of zinc in one daily dose of the composition. The Frankel reference is a review article which provides recommendations for nutritional supplementation for patients undergoing total parenteral nutrition (TPN). In particular, the Frankel reference recommends supplementation of chromium, copper, manganese, selenium, and zinc for most patients on TPN. With respect to selenium, the Frankel reference recommends a "minimum provision" of 50 mcg/day (i.e., 0.05 mg/day) (Frankel reference at page 587, fourth paragraph). The Frankel reference recommends a minimum of 5 mg/day of zinc, and discloses that as much as 10 mg/day of zinc "has been used with good results" (Frankel reference at pate 588, sixth paragraph).

A prior art reference which discloses a range that overlaps or touches a claimed range only anticipates the claimed range if the prior art reference discloses the claimed range with "sufficient specificity" (see M.P.E.P. § 2131.03). For example, if the claims are directed to a narrow range, and a prior art reference discloses a broad range, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an

anticipation of the claims. See, e.g., *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999, 78 U.S.P.Q. 2d 1417, 1423 (Fed. Cir. 2006).

While the Frankel reference discloses compositions comprising a broad range of selenium and zinc concentrations which arguably overlap or touch the ranges of the pending claims, the Frankel reference does not disclose the claimed ranges with "sufficient specificity" to constitute anticipation of the pending claims. In this respect, the Frankel reference discloses administering at least 50 mcg/day of selenium, but does not disclose a recommended maximum dose. In addition the Frankel reference discloses administering a minimum of 5 mg/day of zinc, but that as much as 10 mg/day of zinc could be useful. The Frankel reference, however, does not disclose or remotely suggest providing a composition containing a daily dose of 0.5 mg-2 mg of selenium and 10 mg-100 mg of zinc as presently claimed. Therefore, the Frankel reference does not disclose the claimed dose rage of selenium and zinc with "sufficient specificity" so as to anticipate the subject matter of claims 1-6, 16, and 18-22.

The '863 publication discloses an enteral nutrition composition comprising micronutrients, including selenium and zinc, but excluding iron. Specifically, the composition can comprise about 5 mg-about 10 mg zinc, and about 40 μg-about 100 μg (i.e., about 0.04 mg–about 0.1 mg) selenium. The '863 publication, however, does not disclose a composition comprising 0.5 mg-2 mg of selenium. As such, the pending claims, as amended, are not anticipated by the '863 publication.

In view of the forgoing, Applicants submit that neither the Frankel reference nor the '863 publication anticipates the pending claims, as amended. Accordingly, the Section 102(b) rejections should be withdrawn.

Discussion of Rejections Under 35 U.S.C. § 103(a)

Claims 7 and 8 have been rejected under Section 103(a) as allegedly obvious over the Frankel reference, and claim 17 has been rejected under Section 103(a) as allegedly obvious over the Frankel reference in view of the '863 publication. These rejections are traversed for the reasons set forth below.

For subject matter defined by a claim to be considered obvious, the Office must demonstrate that the differences between the claimed subject matter and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a); see also *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). The ultimate determination of whether an invention is or is not obvious is based on certain factual inquiries including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the prior art, (3) the differences between the claimed invention and the prior art, and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18, 148 U.S.P.Q. at 467.

Consideration of the aforementioned Graham factors here indicates that the present invention, as defined by the pending claims, is unobvious in view of the cited references.

Regarding the scope and content of the prior art, the Frankel reference discloses compositions for total parenteral nutrition (TPN) therapy. In particular, the Frankel reference recommends supplementation of chromium, copper, manganese, selenium, and zinc for most patients on TPN. The Frankel reference recommends a "minimum provision" of 50 mcg/day (i.e., 0.05 mg/day) of selenium (Frankel reference at page 587, fourth paragraph). The Frankel reference recommends a minimum of 5 mg/day of zinc, and discloses that as much as 10 mg/day of zinc can be provided. The '863 publication discloses an enteral nutrition composition comprising micronutrients, including selenium and zinc, but excluding iron. Specifically, the composition can comprise about 5 mg-about 10 mg zinc, and about 40 μg-about 100 μg (i.e., about 0.04 mg-about 0.1 mg) selenium.

For the sake of argument and for purposes of the present analysis, one of ordinary skill in the art can be assumed to be someone with an advanced degree in a relevant field and a few years of experience in the relevant art.

Claims 7 and 8 depend from claim 1, while claim 17 ultimately depends from claim 16. Claims 1 and 16, as amended, require a nutrition trace element composition which contains 0.5 mg-2 mg of selenium and 10 mg - 100 mg of zinc in one daily dose of the composition. The '863 publication does not disclose a composition comprising 0.5 mg-2 mg of selenium. In addition, the Frankel reference does not disclose or remotely suggest

providing a composition containing a daily dose of 0.5 mg-2 mg of selenium and 10 mg-100 mg of zinc as presently claimed. Therefore, the subject matter of claims 1 and 16 is not disclosed or suggested by the Frankel reference or the '863 publication, alone or in combination.

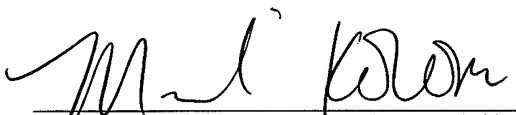
Furthermore, the claimed invention involves surprising and unexpected results. In this regard, Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 of Dr. Thomas Stiefel, which demonstrates that compositions comprising high doses of selenium and zinc (i.e., selenium doses that are ten-fold higher than those disclosed in the prior art), including doses encompassed by the claimed ranges, is associated with a low risk of chronic inflammation, infections, or diseases associated with free-radical production, as compared to low-dose compositions.

Considering all of the Graham factors together, particularly the fact that the combination of the cited references do not disclose all of the elements of the pending claims, and that the claimed invention involves surprising and unexpected results, it is clear that the present invention would not have been obvious to one of ordinary skill in the art at the relevant time in view of the combination of cited references. Accordingly, the obviousness rejections under Section 103 should be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,



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